Health Information Technology Policy Committee
Summary of the January 13, 2010, Meeting

Participants

KEY TOPICS

1. Call to Order

Judy Sparrow welcomed Committee members and reminded the group that this was a Federal Advisory Committee Meeting, and thus was being conducted in public.

2. Opening Remarks

David Blumenthal, National Coordinator for Health Information Technology, welcomed the group and noted that this meeting marked an important point in the implementation of the Health Information Technology for Economic and Clinical Health Act (HITECH) and in the deliberations of the HIT Policy Committee. With this group's help and that of the HIT Standards Committee, two of the three critical regulations have now been published: the interim final rule on certification of EHRs, and the notice of proposed rulemaking on the Center for Medicare and Medicaid's (CMS) EHR incentives. Part of this meeting was devoted to informing this Committee about those regulations and discussing them.

Also, he said that the Office of the National Coordinator (ONC) has completed the plans for allocating all of the discretionary funds that were appropriated for it under the HITECH Act; there are now approved spending programs for all those monies. The Office is receiving a large number of applications and letters of intent, and over the next weeks and months will be announcing awards. David Blumenthal expressed enthusiasm that informatics communities, local and state governments, nonprofits, and academic organizations have all been responding to these opportunities.

3. Review of the Agenda

HIT Policy Committee Co-Chair Paul Tang reviewed the day's agenda, and then asked for and received approval of the minutes from the last meeting (held on December 15, 2009).

> **Action Item #1:** The Committee approved the minutes from last meeting by consensus.

4. Overview of the Notice of Proposed Rulemaking (NPRM) on EHR Incentive

Tony Trenkle began his presentation by noting that there will be additional opportunities over the next several months to provide comments and before the final regulation is prepared for publication later this year. The NPRM was published on the day of this meeting and its public comment period will expire on March 15, 2009. The definition of meaningful use, the definition

of a hospital-based eligible professional, and the incentive programs for Medicare fee-for-service, Advantage, and Medicaid programs are laid out in various sections of the regulation. He noted that the definition of a certified electronic health record (EHR) is critical in developing meaningful use criteria for this program. The NPRM builds a platform that allows for state improvement over time. This Committee was vocal about a staged approach, geared not only to the calendar year, but also the year of entry into the program.

Tony Trenkle presented a series of slides to give the Committee an overview of the NPRM's key features. He explained that meaningful use will be defined in future CMS rulemaking, and that three states have been established, with an "escalator" manner of staging for participants. In year 1, there will be a 90-day reporting period, and in subsequent years the reporting period will last all year. He offered an overview of clinical quality measures, core quality measures for practitioners, and then various specialty measures.

In summarizing the differences in the NPRM between Medicare and Medicaid, he noted that incentives are much higher in Medicaid, and the bar for participation is also higher. He then presented a slide showing the ways in which the NPRM as published differs from the recommendations made by the HIT Policy Committee. The slide detailed deletions, additions, and changes. Most of the differences had to do with documentation of progress notes. The next steps in the NPRM process are as follows:

- Committee input received until March 1
- Public comment period ends March 15
- CMS review of comments
- Drafting of the final regulation
- CMS/Department of Health and Human Services (HHS)/Office of Management and Budget (OMB) clearance
- Final rule published in spring 2010.

Paul Tang, in his role as Chair of the Meaningful Use Workgroup, offered a preliminary response to the NPRM from that group. He explained that the Workgroup will have an all-day meeting on January 28, and will be developing its complete response. He provided some illustrations of the types of comments that the Workgroup will be presenting back to ONC and CMS. Workgroup members are dividing their comments into three areas: (1) broad, philosophical comments; (2) clarification comments; and (3) granular comments on specific elements of the NPRM.

5. Preliminary Thoughts/Discussion on the NPRM

- Tony Trenkle thanked the Meaningful Use Workgroup for its initial input. Additional feedback regarding areas that need clarity is being sought. If something needs to be

changed, the need for that change must be clear, and an alternative must be explained and backed up with data, if possible.

- Additions to the NPRM cannot be proposed. Jodi Daniel of ONC agreed and further explained that if an issue is mentioned either in the regulatory text or the preamble, then it can be commented on.

- Charles Kennedy noted that one objective is to check insurance eligibility electronically. He asked whether the physician who already has a practice management system satisfies this requirement, or whether they physician needs to find an electronic medical record (EMR) that carries out this same function. Farzad Mostashari explained that every one of the meaningful use objectives was included as criteria that need to be met by certified EHR technologies as an aggregate. It is accurate to say that certified technologies must be able to provide that ability; however, the HIT Policy Committee's recommendation on certification was that modular systems be permitted, where a combination of systems would satisfy that requirement.

- Deven McGraw noted that in the Privacy and Security Workgroup, one concern is that many providers have no idea how to conduct a security review. That information could potentially come through the regional educational extension centers, or perhaps from guidance provided by the Office of Civil Rights (OCR). Jodi Daniel indicated that any input from the Privacy and Security Workgroup would be welcomed, as the ONC is developing a program for use by regional extension centers.

- Christine Bechtel noted that the HIT Policy Committee recommended data collection of demographics, but she did not see that in the documentation. Farzad Mostashari explained that there is an expectation that such information could be used for the reduction of disparities, but there is not a requirement for actually using the information. Systems would certainly permit motivated providers to do so, however.

- With regard to the exclusion of patient educational materials, Farzad Mostashari said that the availability of patient educational materials in the marketplace that are at the appropriate health literacy level, are in different languages, and are integrated tightly, is still not there. If there is information that shows that this assessment is actually wrong, it would be extremely valuable.

- Neil Calman noted that it is hoped this type of information will move the industry quickly. The National Library of Medicine is now able to link directly up with problems as well as medications and lab testing. Patients can now link to Medline Plus through their systems, and that is now available through vendors. These are examples of motion that has been created by this discussion.

- It was pointed out that the goal is to improve health care in the United States, more so than it is to have vendors add features. Almost every medical talk includes mention of the correlation of obesity and chronic disease. However, the three core measures mentioned in the NPRM do not touch on the obesity issue.

- Farzad Mostashari reported that many comments suggested that the measures should apply to the providers who are applying for the incentive payments. The three measures that have the broadest applicability to the practitioners who will actually be using them were selected, and providers will be asked to identify another set of measures specific to their specialty (e.g., pediatricians would have the option to communicate which of the measures most applies to their specialty and matters the most). It was noted that geriatrics was selected as a specialty in the core measures, yet pediatrics did not. It was suggested that BMI be used as a measure for everyone, then, not just for pediatric patients.

- Gayle Harrell noted that there are specialties within specialties, and at some point these will need to be examined. Tony Trenkle acknowledged this, and explained that the measures can be refined in future years to account for this.

- Gayle Harrell commented that with regard to help with the privacy and security arena, the regional extension centers are geared for general and family practices, not for specialists. Farzad Mostashari acknowledged that those in small practices, including specialists, are going to have the greatest difficulty. However, regional extension centers will have some valuable tools in an easily digestible format that will be available in the public domain for all users. Regional extension centers are not expected to be the only way for people to access help. Other organizations might include societies and associations, and for-profit entities and market-driven resources that will assist with security and meaningful use issues.

- Neil Calman explained that the glide path of Medicaid is very different than that of Medicare. States that are not well organized and may not be able to access Medicaid dollars will fall further behind those states that are organized about Medicaid, creating a bigger disparity. This is a very different situation than that of Medicare, which is rolling out on a national level.

- Tony Trenkle said that under the law, Medicaid can allocate dollars to states to assist with the development of implementation and plans. CMS is examining ways it can work together with ONC to provide infrastructure to support meaningful use criteria achievement in various states. They have asked each state for a point of contact in the HIT area. Medicaid is holding a conference in February to publicize this information and the funding opportunities that are available.

- Farzad Mostashari noted that there are state grants from ONC of more than $500 million that were planned for the purpose of helping establish infrastructure in states. There is a requirement to have a state HIT Coordinator, and a state HIT plan. The focus is on health information exchange (HIE) infrastructure, but some of the components that are put in place will address HIT adoption.

- Tony Trenkle said that there is a system in place to track those states that are not applying for grants, and not asking for help.

- David Lansky noted that in the original statutory language, the emphasis was on improving efficiency and reducing costs in health care. The explicit references to greater efficiency are mostly missing now. Tony Trenkle explained that this was emphasized in the preamble—and if it is not sufficiently emphasized, it should be looked at again. David Lansky commented that it would be a tremendous disappointment if an emphasis was not placed on the need to include systems for controlling costs.

6. Overview of the Interim Final Rule (IFR) on Initial Set of Standards, Implementation Specifications, and Certification Criteria for EHRs

Farzad Mostashari, Doug Fridsma, and Jodi Daniel presented the IFR to the Policy Committee. Slides showed the principles that guided the certification criteria and standards, an illustrative crosswalk from Meaningful Use Objectives to Certification Criteria to Standards, and the four categories into which the standards have been divided: (1) content exchange standards, (2) vocabulary standards, (3) transport standards, and (4) privacy and security standards.

7. Preliminary Thoughts/Discussion on the IFR

- Paul Egerman asked if the message to the software industry is that this is the blueprint they should use to start building, and it will not change very much. Farzad Mostashari confirmed this.

- Deven McGraw noted that there are technical functionalities that must be in a system for certification, but there is no obligation to actually use them. So, encryption may be required to exist in the system, but a user may decide not to turn it on. On the other hand, if there is a requirement that it could not be turned off, then it is hardwired into the system, although the feasibility of this approach is unclear. For some, use of a particular functionality will depend on whether or not they are required to do so.

- Farzad Mostashari said that it would not be appropriate to make policy moves through certification criteria. Jodi Daniel suggested that there are other levers that can be used. They are required to develop security guidance under ARRA, and there are also some relevant points in HIPAA. She noted that some of these are difficult policy issues: the Standards Committee has indicated that encryption is an important tool, and there are times when it is appropriate, and times when it is not the right tool. It was not an "all or nothing" scenario in some instances.

- Deven McGraw explained that, with regard to the issue of patient choice, there are certain parts of federal and state law today that require patient consent for data to flow. She asked whether, in these instances, a technical functionality that is part of certified systems could help providers to comply with a law that already exists. In response, it was noted that there are technologies available that have electronic means to capture signatures, etc., for patient consent. It is hoped that the HIT Policy Committee will work through how best to incrementally extend these types of technologies.

- It was noted that software developers need to know how to get their products certified. Jodi Daniel explained that this information will be made available as soon as possible.

- Deven McGraw reinforced the point that there needs to be greater interpretive guidance from the Clinical Laboratory Improvement Amendments (CLIA) office to move the labs in a more positive direction.

- Art Davidson asked how states, and particularly public health departments, are lined up to receive data being sent using specific versions of HL-7. He asked if there is an assessment of the current landscape, particularly with regard to the relative levels of some states versus others.

- David Lansky commented on the availability of funds to address the issue that some jurisdictions cannot currently receive the information, or do not have the interest in receiving the information. Meaningful use and the NPRM have the proviso that funding is subject to the satisfaction of applicable public health agency requirements.

- Tony Trenkle noted that CMS is working with ONC to determine how to leverage funding from both agencies to address the issue that some states are more advanced than others.

8. NHIN Workgroup: Recommendations

David Blumenthal noted that two questions arose during discussions earlier in this meaning that have a bearing in this session:

- What approaches can be used to get the states involved in information exchange, given that states vary in their abilities to participate?

- How much exchange is going to be possible given the current infrastructure for exchange?

He noted that there are additional, related questions. For example, if meaningful users are held accountable for moving information around, isn't there an obligation to make it feasible for users to do that? The NHIN Workgroup has been tasked with thinking about the responsibility to create a backbone for exchange. What is the federal role? How far, and in what form, should they push the exchange capability? Is the NHIN, which was created before HITECH was established, a sufficient approach to creating the backbone for interoperability, or should they be thinking more broadly? How can support states, hospitals, and other entities be supported, and how does that relate to making meaningful use possible?

NHIN Workgroup Chair David Lansky noted that there are hundreds of thousands of potential users, and the Workgroup is not confident that it knows who all of the potential user groups are and how to reach all of them. Prior to this meeting, the Workgroup heard two days of testimony; one day focused on directories, the other on authentication. Workgroup members have spent a great deal of time discussing the definition of the NHIN, and developed the following definition:

"A set of policies, standards, and services that enable the Internet to be used for secure and meaningful exchange of health information to improve health and health care."

The Workgroup's charge is to create a set of recommendations for a policy and technical framework for the NHIN in a way that is both open to all and fosters innovation. The NHIN is a set of policies, standards, and services—not a "set of wires" or any type of physical structure. A starting point for the Workgroup is to determine what it can do to help potential meaningful users start exchanging data. In terms of the government's role relative to the NHIN, David Lansky explained that ideally, the government would:

- Recognize (and learn from) existing patterns of exchange
- Create incentives to stimulate information exchange without impeding existing exchange models.
- Foster innovation to achieve new means for information exchange.
- Facilitate long-term expansion of information exchange under a variety of scenarios.

There are key elements that need to be in place to facilitate and encourage the broadest range of providers (individuals and organizations) to achieve meaningful use in 2011. These include: (1) secure Internet transport, (2) directories to allow parties to locate those to whom information is transferred, (3) means to authenticate/validate identity of parties involved in information exchange, and (4) trust fabric that provides parties with sufficient confidence that the exchange can be accomplished successfully.

The Workgroup then presented its recommendations to the Committee in the areas of meaningful use, transport vs. content, directories, and authentication.

The discussion that followed included the following points:

- Adam Clark asked if this work segues into the telemedicine approach, in particular for communities that may not have access to the Internet, but may have access to mobile phones. Do these recommendations apply, or is it that the Internet functions as the firewall? David Lansky indicated that Workgroup members have expressed a willingness to embrace a variety of devices in this regard.
- Paul Egerman noted that it is possible to exchange data without actually transporting it; this could simplify many of the issues being addressed by the Committee and the NHIN Workgroup.
- Gayle Harrell commented that within the Workgroup's recommendations, every time there is reference to furthering meaningful use, there should be a mention of privacy and security.

- David Blumenthal noted that these recommendations will guide the ONC in its future directions, and more concrete plans will be developed. For example, the Office will try to initiate pilot programs and develop applications based in large part on the implications that fall from these recommendations.

- With respect to the Workgroup's first recommendation, Jodi Daniel noted that it covers supporting Meaningful Use in the near term, but it only addresses the enabling of providers. If the recommendation is limited just to providers, then it excludes public health authorities.

- It was noted that the fourth recommendation suggests local autonomy in the method of authentication, which seems counterintuitive to a national model. In-person identify validation may be operationalized differently depending on the location.

- Paul Tang noted that the community may have had some preconceived notions about the NHIN. The Workgroup's set of recommendations illustrate a much more permissive system that has core services that must be in place, with core communications going over the Internet.

- It was suggested that the third recommendation indicate that the creation and maintenance of directories should be given local autonomy.

Action Item #2: The recommendations of the NHIN Workgroup were accepted with two amendments:

- The language of the recommendations will be revamped to consistently include mention of privacy and security.

- The third recommendation will indicate that the creation and maintenance of directories should be given local autonomy.

9. HIT Strategic Framework: Preliminary Discussion

HIT Strategic Framework Workgroup Chair Paul Tang, and Co-Chair Jodi Daniel presented an update on the strategic plan process. The Workgroup's findings will be presented as advice to the ONC, and a strategic framework plan will then be drafted and released in the fall of 2010.

Four key themes that have emerged in the development process to date are: (1) meaningful use of HIT, (2) policy and technical infrastructure, (3) privacy and security, and (4) the creation of a learning health system through the effective use of HIT. Privacy and security consistently arose during the development of the draft principles associated with the strategic plan. At the beginning of the document in its current form, a guiding principle is listed explaining that every component of the strategic plan should take privacy and security issues into consideration.

In discussion, the following points were made:

- David Lansky commented that the emphasis on the fourth theme (the creation of a learning health system through the effective use of HIT) is appropriate, this is the "glue" that holds the document together. He asked about reaching a point at which the Committee can say "here is what we are trying to achieve, and here are the major elements needed to get there." The answer to the question of how electronically enabling information flow changes our health is missing from these discussions. He asked about the government's role—is it to create incentives for certain behaviors, technologies, and products?

- Neil Calman stated that there are groups at high levels of adoption and use already in place in some organizations. While the rest of the country is working to adopt meaningful use, there should be another component that supports the front runners. Some of the larger integrated health care systems are already beginning to figure out how to use the technology they have to transform their care, and that creates the map for others to follow.

10. Public Comment

- Robin Raiford, (Eclypsis) characterized the newly published NPRM and IFR as "great bodies of work" and asked if they could be posted online on the Health IT Buzz site.

- Bob Bryant of the Pediatrics Medical Group explained that his organization has used HIT to improve patient outcomes. They have an internally developed system, and from their clinical data warehouse, they are able to improve care and drive research and quality improvement.

- Lindsey [last name unclear] from the American Dietetic Association noted that the foundational themes of ensuring security and privacy as well as engaging consumers keep recurring. Patient communication can be included in meaningful use by handing some of it to non-physician providers.

- Don May of the American Hospital Association (AHA) expressed his hope that the ONC and HIT Policy Committee will help provide flexibility with regard to meaningful use rules. He also voiced concern about the "all-or-nothing" approach that has been put in the proposed rule—this approach has to change if it is to provide an incentive to the providers. He commented that the timeframe is unrealistic; the AHA has surveyed 3,300 hospitals on IT, and found that there are less than 50 hospitals today that have in place the Meaningful Use objectives.

- Tim McNamar, from E-Service, suggested that the use of social networks to change behavior be added to the fourth Strategic Framework theme.

SUMMARY OF ACTION ITEMS:

- **Action Item #1:** The Committee approved the minutes from last meeting by consensus.

- **Action Item #2:** The recommendations of the NHIN Workgroup were accepted with two amendments:
    - The language of the recommendations will be revamped to consistently include mention of privacy and security.
    - The third recommendation will indicate that the creation and maintenance of directories should be given local autonomy.